

**REMARKS**

Claims 1-10 stand rejected in the subject application. New claims 11-20 have been added and find support throughout the specification, such as at page 4, line 24 to page 5, line 3, page 6, lines 1-17, page 8, lines 25-31, and in the originally filed claims. Applicants submit that no new matter has been introduced by the addition of the new claims.

A. Rejection of Claims 1-7 and 9-10 under 35 U.S.C. § 102(b)

Claims 1-7 and 9-10 stand rejected under 35 U.S.C. §102(b) as assertedly being anticipated by EP 0373201 to Cummings (hereinafter "Cummings"). Applicants traverse this rejection for the reasons set forth herein.

Independent claim 1 and the claims that depend therefrom, recite a method of disinfecting or sterilizing an article. The method comprises: placing the article into a chamber; reducing pressure in the chamber to a first pressure; introducing a mist comprising a sterilant into the chamber; and diffusing the mist through the chamber into contact with the article. Claim 1 further recites that the first pressure is below atmospheric pressure and above the vapor pressure of the sterilant whereby to enhance diffusion of the mist throughout the chamber.

The Examiner asserts that Cummings teaches each and every element recited in claim 1 of the subject application. In particular, the Examiner asserts that Cummings discloses a vapor hydrogen peroxide sterilization method for treating medical items comprising: placing articles into the chamber, reducing pressure in the chamber to a first pressure that is above hydrogen peroxide vapor pressure and below atmospheric pressure,

introducing a sterilant as a mist into the chamber and diffusing the mist through the chamber into contact with the articles (Office Action, page 2, paragraph 3). Applicants respectfully disagree that Cummings teaches each and every element of claim 1.

In addition to those distinctions already of record, Cummings fails to teach reducing pressure in the chamber to a first pressure wherein the first pressure is below atmospheric pressure (i.e., 760 mm Hg) and above the vapor pressure of the sterilant whereby to enhance diffusion of the mist throughout the chamber, as recited in claim 1. Instead, Cummings teaches reducing the absolute chamber pressure above the vapor pressure of hydrogen peroxide and below the vapor pressure of water to promote the evaporation of water and control the evaporation of the condensate (i.e., hydrogen peroxide) (See, Cummings, page 4, lines 6-27). The pressure conditions taught by Cummings are meant to satisfy a clearly stated objective. Absent the specific low pressure conditions taught by Cummings, the water will not evaporate and will not leave a condensate of concentrated hydrogen peroxide on the cold surfaces (See, Cummings, page 4, lines 8-13 and lines 24-27). Thus, for the Cummings system to function properly, the pressure must be maintained within a very specific, and very low pressure range (0.642 mm Hg to 9.2 mm Hg at 10°C) in order to achieve the clearly stated objective, i.e., to concentrate the hydrogen peroxide and enhance its sterilization capabilities. Thus, it is critical for the system of Cummings to maintain the very narrow absolute pressure range between the vapor pressure of hydrogen peroxide (i.e., 0.642 mm Hg at 10°C) and the vapor pressure of water (i.e., 9.2 mm Hg at 10°C) in order to evaporate water and further concentrate the hydrogen peroxide sterilant.

Importantly, and as set forth at page 4, lines 6-8 of Cummings, it is only through continued injection of vapor phase hydrogen peroxide that Cummings establishes a flow-through system that allows hydrogen peroxide to diffuse through the chamber.

Accordingly, in this regard, Cummings teaches a conventional forced/positive pressure sterilizing delivery system, as discussed in the present specification at page 5, lines 26-31.

Unlike the teachings of Cummings, the disinfecting or sterilizing method of claim 1 recites, in part, the act of reducing the pressure in the chamber to a first pressure wherein the first pressure is below atmospheric pressure and above the vapor pressure of the sterilant whereby to enhance diffusion of the mist throughout the chamber. In the Applicants' claimed method, a significantly greater pressure (such as set forth in claims 4-6) is employed when compared to the Cummings system in order to enhance the diffusion of the mist throughout the chamber. Cummings clearly does not teach, *inter alia*, reducing the pressure in a chamber to a first pressure to enhance diffusion of the mist throughout the chamber, as recited in claim 1. Indeed, Cummings specifically teaches a conventional delivery system wherein hydrogen peroxide diffuses through the chamber through continued injection of vapor phase hydrogen peroxide to establish a flow-through system.

For a reference to be anticipatory under 35 U.S.C. § 102, it is axiomatic that the reference or combination of references teach, either explicitly or inherently, each and every element of the invention as set forth by the claims. Cummings does not teach a method of disinfecting or sterilizing an article comprising, in part, reducing pressure in the chamber to enhance diffusion of the mist throughout the chamber, as recited in the present claims 1-7

and 9-10. For at least this reason, Cummings does not anticipate independent claims 1 or any of the claims dependent therefrom.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-7 and 9-10 under U.S.C. § 102(b) over Cummings.

In addition, Cummings provides no suggestion of the use of pressure to enhance diffusion of the sterilant throughout the chamber. Indeed, Cummings can be said to teach away from the use of reduced pressure systems that enhance sterilant diffusion throughout the chamber, as recited in the claims of the subject application. Furthermore, modification of the Cummings system to pressures that enhance diffusion of the sterilant throughout the chamber will destroy the intended function of Cummings and will result in the failure to achieve a clearly stated objective, namely to evaporate water and further concentrate the hydrogen peroxide sterilant.

**B. Rejection of Claim 8 under 35 U.S.C. § 103(a)**

Claim 8 stands rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Cummings further in view of U.S. Patent No. 5,785,934 to Jacobs *et al.* (hereinafter "Jacobs"). Applicants respectfully traverse the rejection for at least the reasons as set forth herein.

Cummings is clearly distinct from claim 8, which depends from claim 1, for at least the reasons set forth in Section A, above. Furthermore, Jacobs provides no teaching that, when combined with Cummings, would lead one of ordinary skill in the art to Applicants' claimed method of disinfecting or sterilizing an article comprising, in part, reducing

pressure in the chamber to enhance diffusion of the mist throughout the chamber. Indeed, the Examiner only cites Jacobs for the teaching of inoculating stainless steel blades with *Bacillus stearothermophilus* (Office Action, page 4, paragraph 2).

Thus, a *prima facie* case of obviousness for claim 8 in view of the combination of teachings of Cummings and Jacobs has not been established. Accordingly, Applicants respectfully request the withdrawal of the rejection of claim 8 under 35 U.S.C. §103(a) in view of Cummings and Jacobs.

C. New Claims 11-20

New claims 11-20 have been added and recite a method of disinfecting or sterilizing an article comprising placing the article into a chamber, and reducing pressure in the chamber to a first pressure to disperse a mist throughout the chamber and into contact with the article.

For at least the reasons set forth in Section A, none of the cited references teaches this method. As set forth above, Cummings and Jacobs fail to teach or suggest the methods recited in claims 11-20.

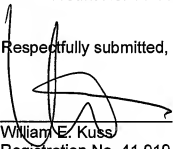
Accordingly, consideration and allowance of claims 11-20 are respectfully requested.

**CONCLUSION**

For at least the reasons discussed above, Applicants respectfully request reconsideration of the rejections of claims 1-10 and allowance of all claims 1-20. Applicants respectfully submit that the present claims are clearly distinguished over the prior art of record and are in proper form for allowance.

If the undersigned can be of assistance to the Examiner regarding any of the above, please contact the undersigned at the number set forth below. Applicants submit that if any additional fee is necessary for consideration of this Response, the Commissioner is hereby authorized to charge the additional required fees to Account No. 11-1110.

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Date

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